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110TH CONGRESS
2D SESSION

H. R. 5468

To amend title XIX of the Social Security Act to provide Medicaid coverage of drugs prescribed for certain research study child participants.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 14, 2008

Mr. SHUSTER (for himself and Mr. PLATTS) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend title XIX of the Social Security Act to provide Medicaid coverage of drugs prescribed for certain research study child participants.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Nino's Act".

SEC. 2. MEDICAID COVERAGE OF DRUGS PRESCRIBED FOR RESEARCH STUDY CHILD PARTICIPANTS.

(a) MANDATORY COVERAGE IF STATE PROVIDES DRUG COVERAGE.—

(1) STATE PLAN REQUIREMENT.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)) is amended—

(A) in paragraph (69), by striking "and" at the end;

(B) in paragraph (70), by striking the period at the end and inserting "; and"; and

(C) by inserting after paragraph (70) the following new paragraph:

"(71) in the case of a State plan that provides medical assistance for prescribed drugs under section 1905(a)(12), provide for such medical assistance to include coverage for any drug, biological product, or insulin prescribed for a child (including any such drug, product, or insulin that is self-administered) who—

"(A) is eligible for medical assistance under the State plan (including a child who is eligible only on the basis of paragraph (10)(A)(i)(VIII));

"(B) is a current or former participant in a research study conducted or funded (in whole or in part) by the National Institutes of Health; and

"(C) satisfies the requirements of subparagraphs (B), (C), and (D) of subsection (dd)(1).".

(2) MANDATORY COVERAGE OF DRUGS OF RESEARCH STUDY CHILD PARTICIPANTS WHO ARE NOT OTHERWISE ELIGIBLE FOR MEDICAID IF THE STATE OFFERS DRUG COVERAGE.—

(A) IN GENERAL.—Section 1902(a)(10)(A)(i) of the Social Security Act (42 U.S.C. 1396b(a)(10)(A)(i)) is amended—

(i) in subclause (VI), by striking "or" at the end;

(ii) in subclause (VII), by adding "or" at the end; and

(iii) by adding at the end the following new subclause:

"(VIII) who are research study child participants described in subsection (dd)(1), but only if the medical assistance made available by the State includes prescribed drugs under section 1905(a)(12),".

(B) GROUP DESCRIBED.—Section 1902 of the Social Security Act (42 U.S.C. 1396a) is

amended by adding at the end the following new subsection:

"(dd)(1) Research study child participants described in this subsection are individuals who—

"(A) are not otherwise eligible for medical assistance under the State plan;

"(B) have not attained age 19;

"(C) have been certified by a physician participating in a research study conducted or funded (in whole or in part) by the National Institutes of Health to be current or former participants in such trial or study who have a specific disease or condition that—

"(i) is or has been successfully treated under such trial or study with a prescribed use of a drug, biological product, or insulin that is not approved under the Federal Food, Drug, and Cosmetic Act; and

"(ii) is likely to continue to be successfully treated with such drug, product, or insulin; and

"(D) do not have other health coverage for such drug, product, or insulin.

"(2) A State shall redetermine not less than every 2 years the eligibility of an individual for medical assist-

ance who is eligible solely on the basis of subsection (a)(10)(A)(i)(VIII).

"(3) For purposes of this subsection and paragraphs (10)(A)(i)(VIII) and (71) of subsection (a), the term 'research study' means a clinical study, including an observational (or natural history) study, or a clinical trial, to test an experimental therapy.".

(C) MEDICAL ASSISTANCE LIMITED TO COVERAGE OF THE RESEARCH OR OBSERVATIONAL TRIAL DRUGS, BIOLOGICAL PRODUCT, OR INSULIN.—Section 1902(a)(10) of the Social Security Act (42 U.S.C. 1396a(a)(10)) is amended in the matter following subparagraph (G)—

(i) by striking "and (XIV)" and inserting "(XIV)"; and

(ii) by inserting ", and (XV) the medical assistance made available to a research study child participant described in subsection (dd)(1) who is eligible for medical assistance solely on the basis of subparagraph (A)(10)(i)(VIII) shall be limited to medical assistance for a drug, biological product, or insulin that is prescribed for the participant as a result of participation

in such trial or study (including any such drug, product, or insulin that is self-administered)" before the semicolon.

(D) CONFORMING AMENDMENT.—Section 1903(f)(4) of such Act (42 U.S.C. 1396b)(f)(4)) is amended in the matter preceding subparagraph (A) by inserting "1902(a)(10)(A)(i)(VIII)," after "1902(a)(10)(A)(i)(VII),".

(b) PRESUMPTIVE ELIGIBILITY.—Section 1920B of the Social Security Act (42 U.S.C. 1396r–1b) is amended—

(1) in the section heading, by inserting "OR RESEARCH STUDY CHILD PARTICIPANTS" after "PATIENTS";

(2) in subsection (a), by inserting "or a child who is eligible for medical assistance under the State plan (including a child who is eligible only on the basis of section 1902(a)(10)(A)(i)(VIII) but subject to the limitation on medical assistance for such a child under clause (XV) of the matter following section 1902(a)(10)(G)), is a current or former participant in a research study conducted or funded (in whole or in part) by the National Institutes of Health, and satisfies the requirements of subpara-

graphs (B), (C), and (D) of section 1902(dd)(1)" after "patients)";

(3) in subsection (b)(1)(A), by inserting "or subsection (a)" after "1902(aa)"; and

(4) in subsection (d), in the flush language following paragraph (2), by striking "for purposes of clause (4) of the first sentence of section 1905(b)" and inserting "for purposes of the first sentence of section 1905(b) (and, in the case of medical assistance furnished to an individual described in section 1902(aa), for purposes of clause (4) of such sentence)".

(c) NOTICE OF MEDICAID COVERAGE FOR RESEARCH STUDY CHILD PARTICIPANTS.—

(1) IN GENERAL.—Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with the Director of the Institutes of Health and State Medicaid Directors, shall—

(A) develop a written notice for child participants in research studies (as defined in section 1902(dd)(3) of the Social Security Act, as added by subsection (a)(2)(B)) conducted or funded (in whole or in part) by the National Institutes of Health who are likely to eligible for

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medical assistance for a drug, biological product, or insulin prescribed for such participants as a result of participation in such a study (including any such drug, product, or insulin that is self-administered) in accordance with paragraph (10)(A)(i)(VIII) or (71) of section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)) (as added by subsection (a)), of the availability of such assistance; and

(B) establish procedures for making such notice available to the child participants through physicians participating in such research studies or such other means as the Secretary determines appropriate.

(2) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated for fiscal year 2008 and each fiscal year thereafter such sums as may be necessary to carry out this subsection.

(d) EFFECTIVE DATE.—The amendments made by this section apply to medical assistance for items and services furnished on or after the date of enactment of this Act, without regard to whether final regulations to carry out such amendments have been promulgated.

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